



The Chemical Company

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**360751**

**Via Federal Express**

TSCA Confidential Business Information Center (7407M)

EPA East - Room 6428 Attn: Section 8(e)

U.S. Environmental Protection Agency

1201 Constitution Avenue, NW

Washington, DC 20004-3302

**Subject:** Notice in Accordance with TSCA Section 8(e): Results of an In Vitro Test on Eye Corrosion/ Severe Irritation and Non-Irritants: Bovine Corneal Opacity and Permeability (BCOP) Test with N-Dibutylpropanamide (CASRN 1187-33-3)

Dear Section 8(e) Coordinator:

BASF Corporation is submitting the results of an In Vitro Test on Eye Corrosion/ Severe Irritation and Non-Irritants: Bovine Corneal Opacity and Permeability (BCOP) Test with N-Dibutylpropanamide (CASRN 1187-33-3), conducted by BASF SE, Ludwigshafen, Germany.

The potential of N,N-Dibutylpropanamide to cause ocular irritation or serious damage to the eyes was assessed by a single topical application of 750 µL of the undiluted test substance to the epithelial surface of isolated bovine corneas.

Three corneas were treated with the test substance for 10 minutes followed by a 2-hours post-incubation period. In addition to the test substance a negative control (NC; de-ionized water) and a positive control (PC; 100% dimethylformamide) were applied to three corneas each.

Corneal opacity was measured quantitatively as the amount of light transmitted through the cornea. Permeability was measured quantitatively as the amount of sodium fluorescein dye that passes across the full thickness of the cornea. Both measurements were used to calculate an *In Vitro* Irritancy Score (IVIS) of the test substance.

In addition H&E-stained cross sections of the corneas were evaluated histopathologically for the irritation potential of the test substance.

The following results were obtained in the BCOP Test:

*Table 1: Mean values for opacity, permeability and IVIS of the test substance, NC and PC.*

	Mean Opacity Value	Mean Permeability Value	Mean In Vitro Irritancy Score
Test substance	6.8	0.465	13.8
NC	1.2	0.005	1.2
PC	109.4	0.955	123.7

Histopathological evaluation: the test substance led to histological scores of irritation (HSI) of IV in all corneas, meaning severe effects on the tissues. Based on that result the test substance was assessed to be severely eye irritating - despite of an IVIS score <55.



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BASF Corporation understands that reporting of the results from this study under TSCA 8(e) is in accordance with EPA's policy.

Please note the technical contact and address below and direct all correspondence regarding this submission accordingly. If you have any questions, please call (248) 948-2051.

Sincerely,

Technical Contact: Alisa Boucher

A handwritten signature in cursive script that reads "Alisa Boucher".

BASF Corporation  
Product Regulatory Center of Expertise – North America  
26701 Telegraph Road, Southfield, MI 48033

1733<sup>rd</sup>

From: (248) 948-2051  
 Alisa Boucher  
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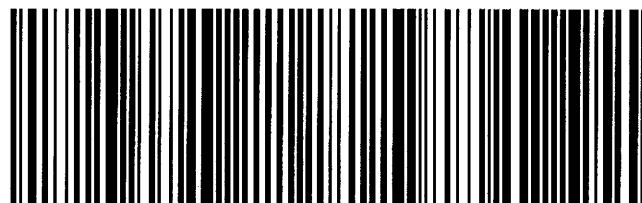
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